Kickstarting the Brain: Regulatory Aspects of New Emerging Technologies

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Agenda

• Is a CE mark sufficient?

• Differences between US and EU regarding Medical Devices (MD)

• Experiences at BfArM with approval of clinical trials

• Regulatory Experience with Esketamine

• How do we deal with innovative approaches in the future
Different Systems in the US and EU

- In EU no formal approval of Medical Devices (MD) based on benefit-risk-assessment by regulatory agencies like BfArM or EMA
- Since 2010 a clinical investigation/performance evaluation for MDs need approval by a competent authority BfArM, and for affirmative evaluation to the competent Ethics Committee

- CE mark based on conformity assessment by notified bodies

- Regulators responsible for vigilance issues: incidents and SAEs are monitored and companies asked for corrective measures

- New regulation process started after serious problems with
  - faulty silicone breast implants (PIP)
  - metal-on-metal (MoM) hip replacement implant devices
  - stent implants
New Medical Device Regulation (MDR) underway

- Current Status (1)


- Key issues of new Regulation
  - Focus still on CE mark
    - conformity assessment depending on risk class
    - all high-risk medical devices (among them all critical implants) will have to undergo premarketing testing by specially qualified notified bodies
  - Strengthening the requirements and responsibilities of notified bodies
New Medical Device Regulation (MDR) underway
- Current Status (2)

• EU-wide seal of quality and approval, for instance ‘CE\textsuperscript{Med}’

• Stronger surveillance:
  • mandatory, unannounced, random control of implants and Class III and IIb devices
  • improvement of medical device traceability

• Scrutiny procedure – intensive assessment by expert group

• Separate In Vitro Diagnostic Medical Devices Regulation, IVDR
Clinical Trials with MDs

• **Deep brain stimulation**
  - Parkinson’s Disease
  - MDD, TRD
  - Substance Abuse
  - Tourette-Syndrome
  - OCD

• **Transcranial stimulation**
  - MDD
  - Epilepsy

• **Vagus nerve stimulation**
  - MDD, TRD

• **No clinical trial using ECT, alone or combination with medicinal products**
  - Not considered as high risk procedure
Guidance for clinical practice?

• Learned societies providing expert guidelines and consensus statements

• Pressure coming by Health Technology Assessment

• Pressure coming by Payers

• They want to see better evidence

• Arguments by industry:
  • Fast moving, innovative field
  • Too much regulation will hinder innovation
Center for Translational Medicine (CTM) Partnership of Research Facilities
Innovation Office at BfArM

• Early scientific advice to applicants with limited resources/regulatory experience
  • Start ups
  • SMEs
  • Academic centers

• Medical Devices
• Combination Products
• Medical Apps, Wearables
Ketamine Story in MDD

- **Pub Med-Hits**
  - ketamine and depression \( n = 1463 \)
  - ketamine treatment resistant depression \( n = 265 \)
  - ketamine suicidal \( n = 64 \)

- **Several SciAdv Procedures**
  - Acute/continuation treatment
  - Different application forms of ketamine
  - Benefit-risk assessment
    - Balance between medical need and risk of abuse
    - Maintenance of effect

- **Regulators proactive and open-minded**
Conclusion:

- Device regulation still different between US and EU
  - EU Regulators responsible for approval of clinical trials and vigilance after market access

- Early Scientific Advice in MD helpful

- New approaches in indications with high unmet medical need welcomed

- Open for new approaches
  - Fostering more exchange between industry, academia and patients
Thank You Very Much For Your Attention!

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